



FORM OF INFORMATION AND INFORMED WRITTEN CONSENT

Order of 8 of Julio 2009 (BOJA nº 152 of date August 6) for which instructions are dictated to the Centers of the Sanitary Public System of Andalusia, in relation to the procedure of Informed Consent.

1. DOCUMENT OF INFORMATION FOR THORACENTESIS

This document serves so that you, or who represents it, give its consent for this intervention. That means that it authorizes us to carry out it.

You can to retire this consent when you want it. To sign it doesn't force you to be made the intervention. Of their rejection he/she won't be derived any adverse consequence regarding the quality of the rest of the received attention. Before signing, it is important that you read the following information slowly.

Tell us if he/she has some doubt or he/she needs more information. We will assist him/her with a lot of pleasure.

1.1 WHAT YOU SHOULD KNOW:

ON WHAT IT CONSISTS?. FOR WHAT REASON IT SERVES?:

Thoracentesis is a procedure aimed to remove fluid that is abnormally accumulated between the two pleuras that surround the lungs. It is performed by a needle (similar to blood extraction) inserted through the chest wall.

Sampling of pleural liquid collected is necessary to be analyzed and to make a diagnosis, although in others occasions the physicians will take out a greater amount of liquid to make you breathe better. In therapeutic thoracentesis, we don't remove more than 1300-1500 c.c. in the same session, because the extraction of much more liquid may produce thoracic pain, or breathing troubles. This discomfort is usually transient and it disappears after a few hours. In occasions it can specify of the use of an exploration with ultrasound (ecography) of the thorax or of a scanner to locate the area of more appropriate puncture.

HOW IS IT CARRIED OUT?

This procedure is generally carried out with local anesthesia in the area of the puncture. With the habitually seated patient, after disinfection of the puncture area and under sterile conditions, the area is anesthetized and it is carried out the puncture among 2 ribs with needle or fine catheter to obtain a sample of liquid of the cavity pleural.

WHAT EFFECTS IT WILL PRODUCE TO YOU?

- You will notice the nuisances characteristic of a jab.
- Sometimes, to locate the liquid it can be necessary to realize more than a jab.
- Fluid draining it is only a palliative measure and the final disappearance of the liquid depends on the treatment of the illness that caused the effusion. For this reason, after draining, pleural effusion can appear again and a new thoracentesis can be necessary.



IN WHAT IT WILL BENEFIT TO YOU?

If it is a thoracentesis therapeutic, it will help you to breathe well.

If it is diagnostic, it will facilitate to arrive to a diagnosis of their illness and therefore to an appropriate treatment.

OTHER AVAILABLE ALTERNATIVES IN YOUR CASE?

Thoracentesis is the first step and the easiest way to determine the cause of a pleural effusion.

It is the election and simpler test to be able to analyze the liquid pleural and power to arrive to a diagnosis. It is also the election technique and simpler to evacuate the liquid pleural.

WHAT RISKS DOES IT HAVE?

Any medical performance has risks. Most of the times the risks are not materialized, and the intervention doesn't produce damages or secondary undesirable effects. But sometimes this is not possible. For that reason it is important that you know the risks that it can appear in this process or intervention.

THE MOST FREQUENT:

- Sometimes is necessary more than one puncture to locate the liquid.
- A vagal reaction could happen frequently. It consists in general discomfort, sweating and bradycardia.
- Local pain or referred to the neck
- When the needle is removed, liquid could come out through the puncture site.

THE MOST SERIOUS:

- Rarely, a vessel or the lung could be punctured. If it happens, hemothorax (step of blood to the cavity pleural) or pneumothorax (step of air to the cavity pleural) may appear. They rarely happen. In these cases, a syringe or a small tube connected to a vacuum bottle may be needed to drain the fluid or the air.
- An infection of the pleural fluid could be produced as a result of the technique very rarely.
- Accidental Punción of the liver, spleen or kidneys.
- Possible risks of the local (allergic serious reaction to the local anesthetics that can end up producing anafilactic shock) anesthesia. These complications habitually are solved with medical treatment (medications, serums, etc.) but they can end up requiring other emergency procedures.

THOSE DERIVED OF YOUR PROBLEMS OF HEALTH:

- If you have problems of clotting or of platelets disease, there will be more risk of having bled.
- If you suffer chronic illnesses as heart failure, chronic obstructive pulmonary disease (COPD), diabetes, chest angina, arterial hypertension, etc, the risk can be bigger.

Due to your own characteristics, there are the following additional risks:



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SPECIAL SITUATIONS THAT SHOULD BE KEPT IN MIND

If you have some medical problem related with the clotting of the blood or taking some medication that affects to the same one, it can be necessary to retard this procedure until improving the clotting.

OTHER INFORMATIONS OF INTEREST (to consider for the professional)

OTHER QUESTIONS FOR THOSE THAT WE REQUEST YOUR CONSENT

- Sometimes, during the intervention, accidental discoveries take place. They can force to have to modify the form of to make the intervention and to not use variants of the same one contemplated initially.

- It is sometimes necessary to take biological samples to study their case well. They can be conserved and used later on to carry out investigations related with the illness that you suffer. They were not used directly for commercial ends. If they will be used for other different ends you would be requested the expressed consent later on for it. If he/she doesn't give their consent to be used in investigation, the samples will be destroyed once they stop to be useful to document their case, according to the norms of the center. Anyway, it will be protected the confidentiality appropriately in all moment.

- It can also be necessary to take images, as pictures or videos. They are good to document the case well. They can also be used for educational ends of diffusion of the scientific knowledge. Anyway they will be used if you give their authorization. Their identity will always be preserved in a confidential way.

1.2. EXPLANATORY IMAGES:

In this space they will be been able to insert with character explanatory optional images, anatomical outlines, pictograms etc. that they facilitate and allow to explain in a simpler way the information to the patient.



2. INFORMED WRITTEN CONSENT

2.1. DATA OF THE / OF THE PATIENT AND DE THEIR REPRESENTATIVE (ONLY IN CASE OF INABILITY OF THE / OF THE PATIENT)

Patient name&lastname

Document of identity/Passport number

Deputy name&lastname

Document of identity/Passport number

2.2. PROFESSIONALS THAT INTERVENE IN THE PROCESS OF INFORMATION AND/OR CONSENT

Name&lastname

Date

Signature

Name&lastname

Date

Signature

Name&lastname

Date

Signature

Name&lastname

Date

Signature



2.3. CONSENT

I, Mr / Mrs/Miss_____ manifesto that I am according with the intervention that I have been proposed. I have read and understood the previous information. I have been able to ask and to clarify all my doubts. For that reason I have taken conscious and freely the decision of authorizing it. I also know that I can retire my consent when it estimates it opportune.

☐ Yes ☐ No I authorize to that are carried out the opportune performances, including modifications in the form of carrying out the intervention, to avoid the dangers or potential damages for the life or the health that could arise in the course of the intervention.

☐ Yes ☐ No I authorize the conservation and later use of my biological samples directly for related investigation with the illness that I suffer.

☐ Yes ☐ No I authorize that, in case my biological samples will be used in other different investigations, the investigators contact me to request me consent.

☐ Yes ☐ No I authorize the use of images with educational ends or of diffusion of the scientific knowledge.

NOTE: Mark you with a cross.

Córdoba (Spain), month/day...../Year 201__

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Physician signature

.....
Patient/deputy signature
(only if patient's inability)



2.4. REJECT OF THE INTERVENTION

I, Mr / Mrs / Miss, I don't authorize to the realization of this intervention. I assume the consequences that of they can be derived for the health or the life.

Córdoba (Spain), month/day...../Year 201__

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Physician signature

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Patient/deputy signature
(only if patient's inability)

2.5. CONSENT REVOCATION

I, Mr / Mrs / Miss, in a free and conscious way I have decided to retire the consent for performing this intervention. I assume the consequences that of they can be derived for the health or the life.

Córdoba (Spain), month/day...../Year 201__

Physician name

Patient/deputy name

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Physician signature

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Patient/deputy signature
(only if patient's inability)